

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

(Attorney Docket No. TEVE 111US)

Serial No.	: 10/594,861	Docket No	: TEVE-111US
Applicant	: Ashley, et al.	Filed	: 12-5-2007
Examiner	: RICCI, CRAIG D.	Art Unit	: 1614
Title	: Heat Sterilization of Glucocorticosteroids		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Declaration under 37 CFR § 1.131

Sir:

We, Dr. Adrian Ashley, Ph.D. (Cheshire, GB), Dr. Paul Lamb, Ph.D. (Cheshire, GB), Dr. Donald MacDonald, Ph.D. (Cheshire, GB), Dr. John Miller, Ph.D. (Cheshire, GB), Dr. Martin J. Oliver, Ph.D. (Cheshire, GB) and Dr. Mathew Pollard, Ph.D. (Cheshire, GB) hereby declare the following:

1. We are the inventors for the above-identified US Patent Application Serial No. 10/594,861 (hereinafter, "the '861 application"), which has been assigned to Norton Healthcare Ltd.
2. We understand that the Examiner has cited Gentile *et al.*, US Patent Publication No. 2006/0140816 (hereinafter, "the Gentile reference") in rejecting the pending claims of the '861 application. We further understand that the Gentile reference claims priority

from International (PCT) Application No. PCT/EP04/50235, filed March 2, 2004, and published in English.

3. We reduced the invention claimed in the '861 application to practice prior to March 2, 2004. Exhibits A and B, attached hereto, provides a copy of two series of laboratory notebook pages that provide the original record of experiments that support the reduction to practice of our invention. All of the experiments recorded on the lab notebook pages reproduced in Exhibits A and B were recorded contemporaneously with the conduction of those experiments in accord with our standard laboratory notebook practice. All of the experiments recorded on the lab notebook pages in Exhibits A and B were carried out prior to March 2, 2004, and all the laboratory notebook pages in Exhibits A and B were dated and witnessed prior to March 2, 2004.
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Dated: _____, 2010

Dr. Adrian Ashley

Dated: _____, 2010

Dr. Paul Lamb

Dated: _____, 2010

Dr. Donald MacDonald

Dated: _____, 2010

Mr. Dr. John Miller

Dated: 15 JUNE 2010

C. J. Oliver

Dr. Martin J. Oliver

Dated: _____, 2010

Dr. Mathew Pollard

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Dated: _____, 2010

Dr. Adrian Ashley

Dated: 8/6, 2010


Dr. Paul Lamb

Dated: _____, 2010

Dr. Donald MacDonald

Dated: _____, 2010

Dr. John Miller

Dated: _____, 2010

Dr. Martin J. Oliver

Dated: _____, 2010

Dr. Mathew Pollard

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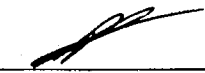
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Dated: 10 June, 2010


10 June 2010

Dr. Adrian Ashley
MR

Dated: _____, 2010

Dr. Paul Lamb

Dated: _____, 2010

Dr. Donald MacDonald

Dated: _____, 2010

Dr. John Miller

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Dated: 11th June 2010

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Dated: _____, 2010

Dr. Martin J. Oliver

Dated: 14 JUN, 2010

M. Pollard
Dr. Mathew Pollard

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from International (PCT) Application No. PCT/EP04/50235, filed March 2, 2004, and published in English.

3. We reduced the invention claimed in the '861 application to practice prior to March 2, 2004. Exhibits A and B, attached hereto, provides a copy of two series of laboratory notebook pages that provide the original record of experiments that support the reduction to practice of our invention. All of the experiments recorded on the lab notebook pages reproduced in Exhibits A and B were recorded contemporaneously with the conduction of those experiments in accord with our standard laboratory notebook practice. All of the experiments recorded on the lab notebook pages in Exhibits A and B were carried out prior to March 2, 2004, and all the laboratory notebook pages in Exhibits A and B were dated and witnessed prior to March 2, 2004.
4. The laboratory notebook pages included in Exhibits A and B are copies of the original record of the experiments described, and the results obtained, in Example 1 of the '861 application. These experiments were carried out in the laboratory facilities of Teva Runcorn, Aston Lane North, Whitehouse Vale Industrial Estate, Preston Brook Runcorn, UK according to the process claimed in the '861 application. The experiments described in the Exhibits were carried out by, or under the supervision of, one or more of us, the inventors of the subject matter claimed in '861 application.
5. The lab notebook pages (notebook LB137, pages 1-13) provided in Exhibit A were signed by Dr. Mathew Pollard (one of the inventors named in the '861 application), as either the author or reviewer. These pages provide a copy of the original record of our preparation of the concentrated budesonide samples that were discussed in Example 1 and summarized in Table 1 at page 4 of the '861 application. Pages 1-4 of Exhibit A show the calculations for the stoichiometry of the concentrates A, B, C and D. Pages 7-9 of Exhibit A provide the record of the preparation of these four concentrates. Pages 10-13 provide details of the heating vessel and the heating regimen. The heating regimen recorded at notebook page 11 in Exhibit A (and the

record of its execution on pages 12-13) correspond to the heating regimen in the right column of Table 1 in the '861 application.

6. The lab notebook pages (notebook LB101, pages 125-135) provided in Exhibit B, were signed by Dr. Paul Lamb (one of the inventors named in the '861 application). These pages provide a copy of the original record of some of the analytical data for the heat sterilization of the budesonide concentrates prepared as recorded in notebook LB137, pages 1-13 (see, the reference to LB137, for example at LB101, page 126, lines 3-6). Pages 127 and 128 provide the HPLC method used for analysis of the budesonide concentrates that had been heat sterilized according to Example 1. The HPLC data for concentrate A is tabulated on LB101, page 131 and corresponds to the data in Table 2, page 5 of the '861 application. Likewise, the data recorded on notebook pages 132-135 for concentrates B, C and D corresponds to the data in Tables 3, 4 and 5, respectively in the '861 application.
7. Also provided here, as Exhibit C, is a copy of the development protocol which was prepared at the time the experiments in notebook LB137, pages 1-13 (Exhibit A) were conducted, and just before the analytical results in notebook LB101, pages 125-135 (Exhibit B) were obtained. The development protocol, which was authored by Dr. Mathew Pollard (one of the inventors named in the '861 application), refers to the experiments in Exhibit A (see, for example, section 2.0 in the heading of Table 1). The development protocol also refers to the HPLC analyses (discussed in paragraph 5 above). The development protocol also includes, in section 2.4, a reference to the method to be used for particle size analysis in another lab notebook LB083 (not provided here).

We, Adrian Ashley, Paul Lamb, Donald MacDonald, John Miller, Martin J. Oliver and Mathew Pollard, declare under penalty of perjury that the above statements and the statements made in the attached Exhibits are true and correct to the best of our knowledge, information, and belief. We understand that willful false statements and the like are punishable by fine or imprisonment, or both under 18 U.S.C. § 1001), and that

Appl. No. 10/594,861
37 CFR § 1.131 Declaration

such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

Each of us is signing on his own behalf and on behalf of any non-signing inventor.

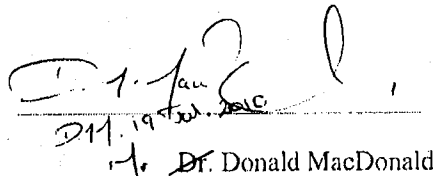
Dated: _____, 2010

Dr. Adrian Ashley

Dated: _____, 2010

Dr. Paul Lamb

Dated: 19 Jul, 2010


Dr. Donald MacDonald

Dated: _____, 2010

Dr. John Miller

Dated: _____, 2010

Dr. Martin J. Oliver

Dated: _____, 2010

Dr. Mathew Pollard